IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: HING et al.	Confirmation No: 8656
Appl. No.	: 09/787,922	
Filed	: June 13, 2002	
Title	: FOAMED CERAMICS	
TC/A.U.	: 1731	
Examiner	: C. Fiorilla	
Docket No.:	: HING3001/REF	
Customer No:	: 23364	

BRIEF ON APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This brief on appeal is submitted in triplicate with the required appeal fee. The period for filing this appeal brief has been extended to expire on October 25, 2003, by the filing herewith of a petition for a one month extension of time and payment of the required fee.

I. REAL PARTY IN INTEREST

The real party in interest is the Assignee of record, Abonetics Limited.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences with respect to the claimed invention which will directly affect or be directly affected by or have a bearing on the

Board's decision in the pending appeal known to appellant, appellant's legal representative or assignee.

III. STATUS OF THE CLAIMS

This application contains claims 1-39. Claims 28-31 have been canceled from the application and are no longer pending. Claims 1-27 and 32-39 are pending and are the claims on appeal. Claims 1-27 and 32-39 stand finally rejected under 35 U.S.C. 103 as prima facie obvious over the prior art cited in the rejections.

IV. STATUS OF AMENDMENTS AFTER FINAL REJECTION

No amendment was filed after Final Rejection.

V. SUMMARY OF INVENTION

The present invention relates to a method for producing a foam ceramic material suitable for use in biomedical applications. (Page 1, lines 1-5. All references to page and line number refers to Applicants' specification.)

Porous bio-ceramic implants offer the potential of tailored-skeletal repair and reconstruction in a variety of orthopaedic procedures, as well as secure fixation of the implant as a result of bony ingrowth and mechanical interlock. (Page 2, lines 8-12.)

The present invention provides a method for the manufacture of porous materials with highly interconnected porosity, which are suitable for use in medical applications. The claimed method provides a synthetic bone material comprising a macro-porous ceramic foam, which has an open foam structure containing pores with a modal diameter $d_{mode} \geq \approx 100$ µm which comprises forming a ceramic slip comprising a substantially homogenous mixture of a ceramic particulate, an organic binder in a liquid carrier, and optionally one or more surfactants. The ceramic slip is foamed by using a

ball mill followed by heating the foam ceramic slip at a temperature sufficient to substantially burn out the organic binder. (Page 3, line 24 to page 4, line 15. See also page 4 at lines 26 and 27 for a discussion of synthetic bone.)

The ceramic slip has most preferably a viscosity of from 30 to 100 $mPas^{-1}$ and it has been found that the viscosity of the slip is important for producing a stable foam, prior to burning out of the binder. (Page 5, lines 6-8.)

The importance of the use of a ball mill is described beginning at page 8, line 21 to page 9, line 10.

The macro-porosity of the sintered ceramic foams produced according to the method of the present invention are highly interconnected as can be seen in Figures 1-3. Further, modal macro-pore size varies with bulk porosity, and ranges from 100 to 2000 μm more typically from 100 to 1000 μm as can be seen in Figures 7 and 8. (See page 12, line 28 to page 13, line 1.)

VI. ISSUES

The issue on appeal is whether or not the combination of references relied upon in the Final Rejection renders the rejected claims prima facie obvious under 35 U.S.C. 103(a).

VII. GROUPING OF THE CLAIMS

The claims as grouped in the Final Rejection do not stand or fall together.

VIII. ARGUMENT

Basic Requirements of a Prima Facies Case of Obviousness

The appellant believes that the criteria set forth in the MPEP provides guidance in determining the issue of obviousness of the claims on appeal.

---SECTION---2143 Basic Requirements of a Prima Facie Case of Obviousness

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

SECTION---2143.03 All Claim Limitations Must Be Taught or Suggested

To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Appellant also most respectfully directs the Examiner's attention to MPEP § 2144.08 (page 2100-130) wherein it is stated that Office personnel should consider all rebuttal argument and evidence present by applicant and the citation of In re Soni for error in not considering evidence presented in the specification.

THE FIRST OBVIOUSNESS REJECTION

The rejection of claims 1, 4 -27, 32,3 and 35-39 under 35 U.S.C. 103(a) as being unpatentable over WO 93/04013 in view of Oishi et al. should be reversed on the grounds that a prima facie case of obviousness has not been established in accordance with the requirements of MPEP 2143.

Claim 1 on appeal is directed to "A method of producing a synthetic bone material for use in biomedical applications, the synthetic bone material comprising a macroporous ceramic foam which has an open foam structure containing pores with a modal diameter $d_{mode} \geq 100$ µm...". Thus, the claimed method is concerned with making a synthetic bone material for biomedical applications (see page 1, lines 1 to 5 of Applicants' specification). There is no specific teaching of this limitation in WO 93/04013 (hereinafter the primary reference) where there is only a passing teaching to "artificial parts for the body" at page 10 of this reference, as a possible product to be formed from a list of more than twenty diversely different products. Applicants note that example III of the primary reference uses hydroxyapatite in a slurry which is aerated using a buchner funnel. Hydroxyapatite is described in the present application, at page 1, and is used in the presently claimed method to produce a synthetic bone material.

As used in the claims on appeal, the term "macroporous" means an open foam structure containing pores with a modal diameter $d_{mode} \geq 100$ µm (see Applicants' specification on page 4, lines 14 to 17). This is a claim limitation which cannot be ignored and is not described or suggested in the primary reference. It is only found in Applicants' specification and in the claims on appeal.

It is further noted that the method according to the primary reference does not appear to result in a porous foamed ceramic structure that would be suitable for use as a biomedical material (e.g. a bone graft substitute) as required by the claims on appeal. For this purpose, the foamed macroporous ceramic material must exhibit open porosity, as opposed to closed porosity, and must have a modal pore size ≥ 100 µm. This is clearly discussed in the description of the present application (see pages 4 and 5) and reflected by the wording of claim 1. Indeed, the reference to the Buchner funnel in

Examples II, III and IV of the primary reference would be expected by one of ordinary skill in the art to result in pores having a similar size to that of the filter, i.e. 10 to 16 μm. Example VIII teaches a slip of hydroxyapatite wherein the product had a mean pore diameter of 24 μm. Moreover, the primary reference states that the pores may be closed and/or the porosity may be open at page 11, second full paragraph. There is no positive teaching in the primary reference of the open pore structure which is a claim limitation of all of the claims on appeal.

Applicants note that the primary reference does refer to gas entrapment by mechanical means and suggests that this may be achieved simply by stirring. This is exemplified in Examples V-X, where a paddle stirrer or stirring in a beaker was used. The other Examples (Example I-IV) rely on a Buchner funnel to produce the foam. It is therefore clear that one of ordinary skill in the art would appreciate that the primary reference had identified what it considered to be suitable methods for forming a foamed ceramic. There is no indication in the primary reference that there were any problems associated with these foaming methods. Accordingly, there simply would not be any motivation for a person skilled in the art to look elsewhere for an alternative foaming technique.

Claim 1 is further limited in that the step of foaming the ceramic slip in step (b) is carried out using a ball mill. The importance of the properties of the synthetic bone material achieved by ball milling in accordance with the claims on appeal is described in Applicants' specification and is not suggested in the prior art relied upon in the rejection. As discussed on pages 8, 9 and 21 of Applicants' specification, there are a number of advantages associated with ball milling foam-stabilised slips formed in accordance with the presently claimed invention including:

(i) No organic sponge/foam template or solid pore-formers to burnout; porous ceramics produced by burnout methods often have relatively low mechanical properties resulting from defects in the structure due to incomplete/irregular burnout of the original template;

(ii) Homogeneous or functionally graduated pore distributions are attainable by varying the slip viscosity;

(iii) Macro-pore size is variable by varying the start-powder particle size; (iv) Macro-porosity is highly interconnected; and

(iv) Microstructure contains an interconnected network of micro-pores, the degree of connectivity of which can be controlled during sintering. This is important for tailoring the drug delivery characteristics of the porous structure.

These advantages enable control of the pore structure so as to minimize batch variation and the production of substantially isotropic open structures. The claimed processing route therefore enables the structural features, such as the pore size and connectivity, of both the macro-porosity and micro-porosity to be tailored to the specific application so that structural and mechanical properties may be matched to particular requirements. It is pointed out that all the Examples featured in the present application rely on the use of a ball mill to achieve foaming of the ceramic slip. Thus, the use of a ball mill is a specific aspect of the invention and not simply an equivalent method of foaming the slip.

Claim 1 differs from the teachings of the primary reference for at least the reasons that this prior art reference does not disclose that the foamed macroporous ceramic material must exhibit open porosity, as opposed to closed porosity, and must have a modal pore size $\geq$100 μm and the step of foaming a ceramic slip using a ball mill (step (b)). It is clear that the primary reference achieves foaming by the injection of gas into the dispersion by either mechanical means e.g. stirring or using a filter of defined pore size, see page five, first paragraph of the primary reference.

In an effort to overcome one of the deficiencies of the primary reference, the Final Rejection relies on the teachings of the '897 patent for foaming by ball milling. However, the '897 patent is directed to a light-weight ceramic acoustic absorber for use in the exhaust nozzles of a jet engine. This absorber has a dense layer provided on the surface of the foamed ceramic, including ceramic fibers as stated at column 2, lines 55-57 which is distinctly different from the structure formed by the process of the present

invention as would be appreciated by one of ordinary skill in the art. It is, accordingly, clear that '897 lies in a completely different technical field from that of the present invention, i.e. synthetic bone materials for biomedical applications. Applicants most respectfully submit that the skilled person, seeking to improve the properties of a ceramic foam for biomedical applications, would not modify the disclosure of the primary reference based on the teaching of the '897 patent related to forming an acoustic absorber to obtain the presently claimed invention. In particular, there is no suggestion in either the primary reference or the '897 patent that the use of a ball mill to achieve foaming of a ceramic slip would result in an improved biomedical ceramic material. Accordingly, there would be no motivation for the skilled person to combine the teachings of the primary reference with the '897 patent, absent Applicants' teaching. In re Fritch, 23 USPQ 1780, 1784(Fed Cir. 1992) ("It is impermissible to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps.). Moreover, obvious to try is not the standard of obviousness under 35 USC 103(a).

As stated in MPEP section 2143, the mere fact that references <u>can</u> be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990) (Claims were directed to an apparatus for producing an aerated cementitious composition by drawing air into the cementitious composition by driving the output pump at a capacity greater than the feed rate. The prior art reference taught that the feed means can be run at a variable speed, however the court found that this does not require that the output pump be run at the claimed speed so that air is drawn into the mixing chamber and is entrained in the ingredients during operation. Although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." 916 F.2d at 682, 16 USPQ2d at 1432.). See also supra, *In re Fritch*, 972 F.2d 1260, 23 USPQ2d 1780 (Fed. Cir. 1992) (flexible landscape edging device which is conformable to a ground surface of varying slope not suggested by combination of prior art references).

In this regard, the Examiner states that there need not be a suggestion that the use of a ball mill to achieve foaming of a ceramic slip would result in an improve biomedical material. This statement is specifically traversed as there must be some motivation to combine the teachings other than that provided by an applicant. As already stated, the '897 patent does not disclose a method of producing a synthetic bone material for use in biomedical applications, e.g. for use as a bone graft substitute. There is also no indication that the ceramic according to the '897 patent has an open macroporous structure with a modal pore size ≥ 100 μm, as required by claim 1 on appeal and there is no motivation to combine these teachings absent Applicants' disclosure which may not be used as a teaching reference.

It is further noted that teachings of the primary reference and the '897 patent appear to be inconsistent with respect to the feature of claim 1 on appeal that the foamed macroporous ceramic material exhibits open porosity and has a modal pore size ≥100 μm. Indeed, the reference to the Buchner funnel in Examples II, III and IV of the primary reference would be expected to result in pores having a similar size to that of the filter, i.e. 10 to 16 μm. Example VIII using hydroxyapatite and ultrasonic agitation yields a product having a pore diameter of 24 μm. The Examiner appears to acknowledge that all of the examples in the primary reference that rely on stirring (i.e. mechanical means) to introduce the gas are silent with respect to pore size. The Examiner then suggests that because the primary reference mentions that the porous articles may be used in artificial parts for the body that they would necessarily have the required pore size but gives no basis for this conclusion. This statement is specifically traversed. It is without factual support in any reference or based on sound scientific reasoning.

Clearly, this conclusion is based on hindsight knowledge of the present invention. In any case, it is inconsistent with the teaching of Example III of the primary reference, which relates to hydroxyapatite, i.e. a material that is used for synthetic bone. In this Example, the pore size is given as 10-16 μm. Thus, the primary reference clearly implies to one of ordinary skill in the art that such a pore size (i.e. 10-16 μm) is

acceptable for porous articles for artificial parts for the body. This being the case, there would be no motivation to refer to the '897 patent with a view to obtaining an increase in the pore size. Put another way, one of ordinary skill in the art to which the invention pertains would actually be taught away from applying the teaching of the '897 patent to the primary reference because the pores sizes referred to the '897 patent (for a light-weight ceramic acoustic absorber) would be considered too high in view of Examples III and VIII of the primary reference.

Thus, there would be no motivation for one skilled in the art to combine the references and arrive at the claimed invention. No prima facie case of obviousness of the rejected claims has been established by this combination of references. There is no indication in either reference that ball milling could or should be used to achieve the required macroporous open foam structure, which is necessary for certain biomedical applications. Indeed this feature is clearly precluded by the teachings of the primary reference as would be appreciated by one of ordinary skill in the art to which the invention pertains.

Even in the unlikely event that the documents were combined, neither document teaches or suggests that foamed macroporous ceramic material has open porosity (as opposed to closed porosity) with a modal pore size $\geq$ 100 μm. Even if the combination of the references taught every element of the claimed invention, however, without a motivation to combine, a rejection based on a *prima facie* case of obvious was held improper. The level of skill in the art cannot be relied upon to provide the suggestion to combine references. Al-Site Corp. v. VSI Int'l Inc., 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999). Thus, the combination of references cannot render the claims prima facie obvious.

As noted on page 6 of Applicants' specification the organic binder serves to provide plasticity during forming of the ceramic particulate and green strength in the formed product. It is also noted that all of the examples in Applicants' specification include an organic binder. At page 7, line 5, of Applicants' specification, it is stated that the organic binder will generally be present in a liquid carrier in an amount of from 0.2

to 10 w/v% and more preferably from 0.5 to 6 w/v%. The specific and preferred limitations are specifically set forth in claims 12, 13 and 35 on appeal. There is absolutely no suggestion in the prior art of these specific ranges which are claim limitations. The necessary motivation is not in the prior art to suggest these preferred aspects of the presently claimed invention and for this reason, these claims are further distinguished over the prior art.

The only disclosure in the primary reference to the use of a binder is at page 9 which simply suggests that binders such as resins may be included but there is no suggestion of the specified amounts which are clearly indicated to be preferred embodiments of the presently claimed invention. The examples in the primary reference do not use binders let alone suggest the amounts specified in claims 12, 13 and 35. While the '897 patent describes the use of an organic binder in the paragraph beginning at column 3, line 25, this relates to a foam slurry which is produced by mixing an alumina based ceramic powder, SiC whiskers, and a solution containing a dispersant, an organic binder and a foaming agent in water. This in no way suggests a modification of the primary reference to arrive at the presently claimed preferred binder concentrations as claimed in claims 11, 12 and 35 on appeal.

As discussed at page 20 of Applicants' specification, the results in Table 3 and Figures 7-10 demonstrate how variation in the ratio of ceramic particulate to binder solution variation in both the bulk density (macro-porosity) and the strut density (micro-porosity). The sintered mill-foamed porous ceramics prepared with the greater volume of liquid carrier have lower bulk and strut densities reflecting a more open, inter-connected pore structure with large macro-pores and a larger fraction of micro-porosity. As noted at page 21, the macro-porous ceramic foams according to the present invention have advantages over the prior art cancellous and coral derived materials.

The sintered ceramic foam has a bulk porosity in the range of from 70 to 90% as specifically claimed in claim 37 and a slightly broader range in claim 25. These are specific claim limitations which again are in no way suggested by the prior art. The strut density is specified in claims 26 and 38. Clearly, these limitations are present in the

claims, discussed in the specification, and further distinguish the claimed subject matter over the prior art.

THE SECOND OBVIOUSNESS REJECTION

The rejection of claims 2 and 3 under 35 U.S.C. §103(a) as being unpatentable over the primary reference in view of the '897 patent as applied to claims 1, 4 -27, 32, 33 and 35-39 above, and further in view of Wu, the '562 patent, is also untenable and should be reversed for the reasons discussed above with respect to the combination of the primary reference and the '897 patent. The '562 patent does not overcome the deficiencies of the combination of references relied upon in the first obviousness rejection.

In the Final Rejection, the Examiner states that '562 patent is cited to teach a conventional size of grinding media. However, claim 2 on appeal is not concerned with milling powders using a grinding media. Instead, claim 2 is concerned with foaming a ceramic slip in a ball mill. This differs from the teaching of the '562 patent in that the starting material is a ceramic slip (not a starting powder) and in that the process produces a foam (not a milled powder). These are fundamental differences as would be appreciated by one of ordinary skill in the art to which the invention pertains. As the Examiner has acknowledged, the '562 patent is not concerned with foamed ceramics, nor synthetic bone materials for biomedical applications.

Applicants note that dependent claim 3 defines that the milling media have a diameter in the range of from 10 to 30 mm. This range is not disclosed in the '897 patent. While the '562 patent does mention 13 mm milling media, this is for grinding the starting powder, not for foaming a ceramic slip. There is no teaching or suggestion in any of the documents that such sized milling media could or should be relied on in the formation of a ceramic foam in accordance with the requirement of claim 3, let alone a ceramic foam for a synthetic bone material, where the pores have a modal diameter as specified by the claims on appeal.

The '562 patent relates to a method of improving the properties of ceramic green bodies. While the '562 patent does mention the use of a ball mill, this is not used to prepare a foamed ceramic. Instead, the ball mill is merely used to prepare (i.e. mill) the starting powders. This is clear from column 5, lines 31 to 42, were, the powders are milled and then separated from the grinding media. Only then is a slurry formed by adding deionized water. Thus, the '562 patent merely describes the conventional technique of using grinding media to mill starting powders. The '562 patent is not concerned with foamed ceramics, nor synthetic bone materials for biomedical applications.

In view of the above comments, it is considered that the disclosure of the '562 patent has been taken out of context and does not establish a prima facie case of obviousness for the claimed subject matter and this rejection should be reversed.

THE THIRD OBVIOUSNESS REJECTION

The rejection of claims 2 , 3 and 34 under 35 U.S.C. §103(a) as being unpatentable over the primary reference in view of the '897 patent as applied to claims 1, 4-27, 32, 33 and 35-39, above, and further in view of Nukada et al US 5,395,722, the '722 patent, is also untenable and should be reversed for the reasons discussed above with respect to the combination of the primary reference and the '897 patent. The '722 patent does not overcome the deficiencies of the first obviousness rejection.

With regard to the '722 patent, this reference is even further removed relating as it does to a electrophotographic photoreceptor. Even though the '722 patent does mention the use of a ball mill, this is used to prepare (i.e. mill) an organic perylene pigment. The '722 patent has nothing to do with ceramic powders let alone the preparation of a foamed ceramic bone material for biomedical applications. This reference was located by looking for claimed limitations and then searching the prior art for these limitations. This is improper hindsight reconstruction of the prior art to arrive

at the claimed invention. Accordingly, the Examiner's rejection should most respectfully be reversed.

IX. CONCLUSION

In view of the above arguments, the rejections of the claims on appeal should be reversed. The application should be passed to issue.

Respectfully submitted,

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October 23, 2003

APPENDIX

CLAIMS ON APPEAL

1. A method of producing a synthetic bone material for use in biomedical applications, said synthetic bone material comprising a macroporous ceramic foam which has an open foam structure containing pores with a modal diameter $d_{mode} \geq 100$ µm, which method comprises:

(a) forming a ceramic slip comprising a substantially homogeneous mixture of a ceramic particulate,

an organic binder in a liquid carrier, and

optionally one or more surfactant, wherein at least one surfactant is present if the organic binder does not function as a surfactant;

(b) foaming the ceramic slip using a ball mill; and

(c) heating the foamed ceramic slip at a temperature sufficient to substantially burn out the organic binder.

2. A method as claimed in claim 1, wherein foaming of the ceramic slip is achieved using a ball mill with milling media selected from alumina (Al_2O_3), enstatite ($MgSiO_3$) or zirconia (ZrO_2) balls.

3. A method as claimed in claim 2, wherein the balls of the milling media have a diameter in the range of from 10 to 30 mm.

4. A method as claimed in claim 1, wherein foaming of the ceramic slip is achieved using a ball mill in conjunction with gassing and/or a blowing agent.

5. A method as claimed in claim 1, wherein the ceramic slip has a viscosity in the range of from 30 to 100 mPas.

6. A method as claimed in claim 1, wherein the ceramic particulate is biocompatible.

7. A method as claimed in claim 1, wherein the ceramic particulate comprises one or more of hydroxyapatite, a substituted-hydroxyapatite, a glass, an AW-glass ceramic and/or alumina.

8. A method as claimed in claim 1, wherein the ceramic particulate has a d_{50} of from 1 to 300 μm.

9. A method as claimed in claim 1, wherein the ceramic particulate has a surface area in the range of from 5 to 200 m^2g^{-1}.

10. A method as claimed in claim 1, wherein the organic binder comprises one or more of poly (vinyl alcohol), poly (vinyl pyrrolidone), alginate, poly (lactic acid), poly (vinyl butyral), poly (ethylene glycol) and/or poly (vinyl acetate).

11. A method as claimed in claim 1, wherein the liquid carrier comprises water, propan-2-ol or trichloroethane.

12. A method as claimed in claim 1, wherein the organic binder is present in the liquid carrier in an amount of from 0.2 to 10 w/v%.

13. A method as claimed in claim 12, wherein the organic binder is present in the liquid carrier in an amount of from 0.5 to 6 w/v%.

14. A method as claimed in claim 1, wherein the ceramic slip comprises from 10 to 95 w/v% ceramic particulate.

15. A method as claimed in claim 14, wherein the ceramic slip comprises from 20 to 90 w/v% ceramic particulate.

16. A method as claimed in claim 1, wherein the ceramic slip further comprises one or both of a dispersant and/or a defloculant.

17. A method as claimed in claim 1, wherein prior to burn-out of the organic binder the liquid carrier is allowed to evaporate from the foamed carrier slip.

18. A method as claimed in claim 17, wherein the foamed ceramic slip is heated at a temperature in the range of from 20 to 100°C to facilitate evaporation of the liquid carrier prior to burn-out of the organic binder.

19. A method as claimed in claim 17, wherein the concentration of the organic binder in the liquid carrier is selected such that the percentage of binder remaining after substantially all of the liquid carrier has been evaporated is from 0.5 to 10 w/w%.

20. A method as claimed in claim 19, wherein the concentration of the organic binder in the liquid carrier is selected such that the percentage of binder remaining after substantially all of the liquid carrier has been evaporated is in the range of from 1 to 6 w/w%, preferably from 1 to 4 w/w%.

21. A method as claimed in claim 1, wherein the foamed ceramic slip is cast in a mould having a surface coated with a release agent.

22. A method as claimed in claim 1, wherein burn-out of the organic binder is carried out at a temperature in the range of from 150 to 700°C.

23. A method as claimed in claim 1, further comprising sintering the ceramic foam following burn-out of the organic binder.

24. A method as claimed in claim 23, wherein sintering is carried out at a temperature in the range of from 500 to 1600°C.

25. A method as claimed in claim 23, wherein the sintered ceramic foam has a bulk porosity in the range of from 40 to 95%.

26. A method as claimed in claim 1, wherein the sintered ceramic foam has a strut density in the range of from 60 to 95% of the theoretical density of the ceramic.

27. A method as claimed in claim 23, wherein the sintered ceramic foam has a modal pore size in the range of from 100 to 2000 μm.

32. A method of producing a synthetic bone material as claimed in claim 1, wherein the ceramic slip preferably has a viscosity in the range of from 15 to 200 mPas.

33. A method as claimed in claim 8, wherein the ceramic particulate has a d_{50} of from 1 to 15 μm.

34. A method as claimed in claim 3, wherein the balls of the milling media have a diameter in the range of from 15 to 25 mm.

35. A method as claimed in claim 13, wherein the organic binder is present in the liquid carrier in an amount of from 0.5 to 4 w/v%.

36. A method as claimed in claim 15, wherein the ceramic slip comprises from 40 to 80 w/v% ceramic particulate.

37. A method as claimed in claim 25, wherein the sintered ceramic foam has a bulk porosity in the range of from 70 to 90%.

38. A method as claimed in claim 26, wherein the sintered ceramic foam has a strut density in the range of from 70 to 90% of the theoretical density of the ceramic.

39. A method as claimed in claim 27, wherein the sintered ceramic foam has a modal pore size in the range of from 100 to 1000 μm.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Filed	:	June 13, 2002	
Title	:	FOAMED CERAMICS	
TC/A.U.	:	1731	
Examiner	:	C. Fiorilla	
Docket No.:	:	HING3001/REF	
Customer No:	:	23364	

BRIEF ON APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

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The present invention relates to a method for producing a foam ceramic material suitable for use in biomedical applications. (Page 1, lines 1-5. All references to page and line number refers to Applicants' specification.)

Porous bio-ceramic implants offer the potential of tailored-skeletal repair and reconstruction in a variety of orthopaedic procedures, as well as secure fixation of the implant as a result of bony ingrowth and mechanical interlock. (Page 2, lines 8-12.)

The present invention provides a method for the manufacture of porous materials with highly interconnected porosity, which are suitable for use in medical applications. The claimed method provides a synthetic bone material comprising a macro-porous ceramic foam, which has an open foam structure containing pores with a modal diameter $d_{mode} \geq \approx 100$ µm which comprises forming a ceramic slip comprising a substantially homogenous mixture of a ceramic particulate, an organic binder in a liquid carrier, and optionally one or more surfactants. The ceramic slip is foamed by using a

ball mill followed by heating the foam ceramic slip at a temperature sufficient to substantially burn out the organic binder. (Page 3, line 24 to page 4, line 15. See also page 4 at lines 26 and 27 for a discussion of synthetic bone.)

The ceramic slip has most preferably a viscosity of from 30 to 100 $mPas^{-1}$ and it has been found that the viscosity of the slip is important for producing a stable foam, prior to burning out of the binder. (Page 5, lines 6-8.)

The importance of the use of a ball mill is described beginning at page 8, line 21 to page 9, line 10.

The macro-porosity of the sintered ceramic foams produced according to the method of the present invention are highly interconnected as can be seen in Figures 1-3. Further, modal macro-pore size varies with bulk porosity, and ranges from 100 to 2000 µm more typically from 100 to 1000 µm as can be seen in Figures 7 and 8. (See page 12, line 28 to page 13, line 1.)

VI. ISSUES

The issue on appeal is whether or not the combination of references relied upon in the Final Rejection renders the rejected claims prima facie obvious under 35 U.S.C. 103(a).

VII. GROUPING OF THE CLAIMS

The claims as grouped in the Final Rejection do not stand or fall together.

VIII. ARGUMENT

Basic Requirements of a Prima Facies Case of Obviousness

The appellant believes that the criteria set forth in the MPEP provides guidance in determining the issue of obviousness of the claims on appeal.

---SECTION---2143 Basic Requirements of a Prima Facie Case of Obviousness

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

SECTION---2143.03 All Claim Limitations Must Be Taught or Suggested

To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Appellant also most respectfully directs the Examiner's attention to MPEP § 2144.08 (page 2100-130) wherein it is stated that Office personnel should consider all rebuttal argument and evidence present by applicant and the citation of In re Soni for error in not considering evidence presented in the specification.

THE FIRST OBVIOUSNESS REJECTION

The rejection of claims 1, 4 -27, 32,3 and 35-39 under 35 U.S.C. 103(a) as being unpatentable over WO 93/04013 in view of Oishi et al. should be reversed on the grounds that a prima facie case of obviousness has not been established in accordance with the requirements of MPEP 2143.

Claim 1 on appeal is directed to "A method of producing a synthetic bone material for use in biomedical applications, the synthetic bone material comprising a macroporous ceramic foam which has an open foam structure containing pores with a modal diameter $d_{mode} \geq 100$ µm...". Thus, the claimed method is concerned with making a synthetic bone material for biomedical applications (see page 1, lines 1 to 5 of Applicants' specification). There is no specific teaching of this limitation in WO 93/04013 (hereinafter the primary reference) where there is only a passing teaching to "artificial parts for the body" at page 10 of this reference, as a possible product to be formed from a list of more than twenty diversely different products. Applicants note that example III of the primary reference uses hydroxyapatite in a slurry which is aerated using a buchner funnel. Hydroxyapatite is described in the present application, at page 1, and is used in the presently claimed method to produce a synthetic bone material.

As used in the claims on appeal, the term "macroporous" means an open foam structure containing pores with a modal diameter $d_{mode} \geq 100$ µm (see Applicants' specification on page 4, lines 14 to 17). This is a claim limitation which cannot be ignored and is not described or suggested in the primary reference. It is only found in Applicants' specification and in the claims on appeal.

It is further noted that the method according to the primary reference does not appear to result in a porous foamed ceramic structure that would be suitable for use as a biomedical material (e.g. a bone graft substitute) as required by the claims on appeal. For this purpose, the foamed macroporous ceramic material must exhibit open porosity, as opposed to closed porosity, and must have a modal pore size ≥ 100 µm. This is clearly discussed in the description of the present application (see pages 4 and 5) and reflected by the wording of claim 1. Indeed, the reference to the Buchner funnel in

Examples II, III and IV of the primary reference would be expected by one of ordinary skill in the art to result in pores having a similar size to that of the filter, i.e. 10 to 16 μm. Example VIII teaches a slip of hydroxyapatite wherein the product had a mean pore diameter of 24 μm. Moreover, the primary reference states that the pores may be closed and/or the porosity may be open at page 11, second full paragraph. There is no positive teaching in the primary reference of the open pore structure which is a claim limitation of all of the claims on appeal.

Applicants note that the primary reference does refer to gas entrapment by mechanical means and suggests that this may be achieved simply by stirring. This is exemplified in Examples V-X, where a paddle stirrer or stirring in a beaker was used. The other Examples (Example I-IV) rely on a Buchner funnel to produce the foam. It is therefore clear that one of ordinary skill in the art would appreciate that the primary reference had identified what it considered to be suitable methods for forming a foamed ceramic. There is no indication in the primary reference that there were any problems associated with these foaming methods. Accordingly, there simply would not be any motivation for a person skilled in the art to look elsewhere for an alternative foaming technique.

Claim 1 is further limited in that the step of foaming the ceramic slip in step (b) is carried out using a ball mill. The importance of the properties of the synthetic bone material achieved by ball milling in accordance with the claims on appeal is described in Applicants' specification and is not suggested in the prior art relied upon in the rejection. As discussed on pages 8, 9 and 21 of Applicants' specification, there are a number of advantages associated with ball milling foam-stabilised slips formed in accordance with the presently claimed invention including:

(i) No organic sponge/foam template or solid pore-formers to burnout; porous ceramics produced by burnout methods often have relatively low mechanical properties resulting from defects in the structure due to incomplete/irregular burnout of the original template;

(ii) Homogeneous or functionally graduated pore distributions are attainable by varying the slip viscosity;

(iii) Macro-pore size is variable by varying the start-powder particle size; (iv) Macro-porosity is highly interconnected; and

(iv) Microstructure contains an interconnected network of micro-pores, the degree of connectivity of which can be controlled during sintering. This is important for tailoring the drug delivery characteristics of the porous structure.

These advantages enable control of the pore structure so as to minimize batch variation and the production of substantially isotropic open structures. The claimed processing route therefore enables the structural features, such as the pore size and connectivity, of both the macro-porosity and micro-porosity to be tailored to the specific application so that structural and mechanical properties may be matched to particular requirements. It is pointed out that all the Examples featured in the present application rely on the use of a ball mill to achieve foaming of the ceramic slip. Thus, the use of a ball mill is a specific aspect of the invention and not simply an equivalent method of foaming the slip.

Claim 1 differs from the teachings of the primary reference for at least the reasons that this prior art reference does not disclose that the foamed macroporous ceramic material must exhibit open porosity, as opposed to closed porosity, and must have a modal pore size $\geq$100 μm and the step of foaming a ceramic slip using a ball mill (step (b)). It is clear that the primary reference achieves foaming by the injection of gas into the dispersion by either mechanical means e.g. stirring or using a filter of defined pore size, see page five, first paragraph of the primary reference.

In an effort to overcome one of the deficiencies of the primary reference, the Final Rejection relies on the teachings of the '897 patent for foaming by ball milling. However, the '897 patent is directed to a light-weight ceramic acoustic absorber for use in the exhaust nozzles of a jet engine. This absorber has a dense layer provided on the surface of the foamed ceramic, including ceramic fibers as stated at column 2, lines 55-57 which is distinctly different from the structure formed by the process of the present

invention as would be appreciated by one of ordinary skill in the art. It is, accordingly, clear that '897 lies in a completely different technical field from that of the present invention, i.e. synthetic bone materials for biomedical applications. Applicants most respectfully submit that the skilled person, seeking to improve the properties of a ceramic foam for biomedical applications, would not modify the disclosure of the primary reference based on the teaching of the '897 patent related to forming an acoustic absorber to obtain the presently claimed invention. In particular, there is no suggestion in either the primary reference or the '897 patent that the use of a ball mill to achieve foaming of a ceramic slip would result in an improved biomedical ceramic material. Accordingly, there would be no motivation for the skilled person to combine the teachings of the primary reference with the '897 patent, absent Applicants' teaching. In re Fritch, 23 USPQ 1780, 1784(Fed Cir. 1992) ("It is impermissible to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps.). Moreover, obvious to try is not the standard of obviousness under 35 USC 103(a).

As stated in MPEP section 2143, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990) (Claims were directed to an apparatus for producing an aerated cementitious composition by drawing air into the cementitious composition by driving the output pump at a capacity greater than the feed rate. The prior art reference taught that the feed means can be run at a variable speed, however the court found that this does not require that the output pump be run at the claimed speed so that air is drawn into the mixing chamber and is entrained in the ingredients during operation. Although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." 916 F.2d at 682, 16 USPQ2d at 1432.). See also supra, *In re Fritch*, 972 F.2d 1260, 23 USPQ2d 1780 (Fed. Cir. 1992) (flexible landscape edging device which is conformable to a ground surface of varying slope not suggested by combination of prior art references).

In this regard, the Examiner states that there need not be a suggestion that the use of a ball mill to achieve foaming of a ceramic slip would result in an improve biomedical material. This statement is specifically traversed as there must be some motivation to combine the teachings other than that provided by an applicant. As already stated, the '897 patent does not disclose a method of producing a synthetic bone material for use in biomedical applications, e.g. for use as a bone graft substitute. There is also no indication that the ceramic according to the '897 patent has an open macroporous structure with a modal pore size ≥ 100 µm, as required by claim 1 on appeal and there is no motivation to combine these teachings absent Applicants' disclosure which may not be used as a teaching reference.

It is further noted that teachings of the primary reference and the '897 patent appear to be inconsistent with respect to the feature of claim 1 on appeal that the foamed macroporous ceramic material exhibits open porosity and has a modal pore size ≥100 μm. Indeed, the reference to the Buchner funnel in Examples II, III and IV of the primary reference would be expected to result in pores having a similar size to that of the filter, i.e. 10 to 16 μm. Example VIII using hydroxyapatite and ultrasonic agitation yields a product having a pore diameter of 24 μm. The Examiner appears to acknowledge that all of the examples in the primary reference that rely on stirring (i.e. mechanical means) to introduce the gas are silent with respect to pore size. The Examiner then suggests that because the primary reference mentions that the porous articles may be used in artificial parts for the body that they would necessarily have the required pore size but gives no basis for this conclusion. This statement is specifically traversed. It is without factual support in any reference or based on sound scientific reasoning.

Clearly, this conclusion is based on hindsight knowledge of the present invention. In any case, it is inconsistent with the teaching of Example III of the primary reference, which relates to hydroxyapatite, i.e. a material that is used for synthetic bone. In this Example, the pore size is given as 10-16 µm. Thus, the primary reference clearly implies to one of ordinary skill in the art that such a pore size (i.e. 10-16 µm) is

acceptable for porous articles for artificial parts for the body. This being the case, there would be no motivation to refer to the '897 patent with a view to obtaining an increase in the pore size. Put another way, one of ordinary skill in the art to which the invention pertains would actually be taught away from applying the teaching of the '897 patent to the primary reference because the pores sizes referred to the '897 patent (for a light-weight ceramic acoustic absorber) would be considered too high in view of Examples III and VIII of the primary reference.

Thus, there would be no motivation for one skilled in the art to combine the references and arrive at the claimed invention. No prima facie case of obviousness of the rejected claims has been established by this combination of references. There is no indication in either reference that ball milling could or should be used to achieve the required macroporous open foam structure, which is necessary for certain biomedical applications. Indeed this feature is clearly precluded by the teachings of the primary reference as would be appreciated by one of ordinary skill in the art to which the invention pertains.

Even in the unlikely event that the documents were combined, neither document teaches or suggests that foamed macroporous ceramic material has open porosity (as opposed to closed porosity) with a modal pore size $\geq$ 100 µm. Even if the combination of the references taught every element of the claimed invention, however, without a motivation to combine, a rejection based on a *prima facie* case of obvious was held improper. The level of skill in the art cannot be relied upon to provide the suggestion to combine references. Al-Site Corp. v. VSI Int'l Inc., 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999). Thus, the combination of references cannot render the claims prima facie obvious.

As noted on page 6 of Applicants' specification the organic binder serves to provide plasticity during forming of the ceramic particulate and green strength in the formed product. It is also noted that all of the examples in Applicants' specification include an organic binder. At page 7, line 5, of Applicants' specification, it is stated that the organic binder will generally be present in a liquid carrier in an amount of from 0.2

to 10 w/v% and more preferably from 0.5 to 6 w/v%. The specific and preferred limitations are specifically set forth in claims 12, 13 and 35 on appeal. There is absolutely no suggestion in the prior art of these specific ranges which are claim limitations. The necessary motivation is not in the prior art to suggest these preferred aspects of the presently claimed invention and for this reason, these claims are further distinguished over the prior art.

The only disclosure in the primary reference to the use of a binder is at page 9 which simply suggests that binders such as resins may be included but there is no suggestion of the specified amounts which are clearly indicated to be preferred embodiments of the presently claimed invention. The examples in the primary reference do not use binders let alone suggest the amounts specified in claims 12, 13 and 35. While the '897 patent describes the use of an organic binder in the paragraph beginning at column 3, line 25, this relates to a foam slurry which is produced by mixing an alumina based ceramic powder, SiC whiskers, and a solution containing a dispersant, an organic binder and a foaming agent in water. This in no way suggests a modification of the primary reference to arrive at the presently claimed preferred binder concentrations as claimed in claims 11, 12 and 35 on appeal.

As discussed at page 20 of Applicants' specification, the results in Table 3 and Figures 7-10 demonstrate how variation in the ratio of ceramic particulate to binder solution variation in both the bulk density (macro-porosity) and the strut density (micro-porosity). The sintered mill-foamed porous ceramics prepared with the greater volume of liquid carrier have lower bulk and strut densities reflecting a more open, inter-connected pore structure with large macro-pores and a larger fraction of micro-porosity. As noted at page 21, the macro-porous ceramic foams according to the present invention have advantages over the prior art cancellous and coral derived materials.

The sintered ceramic foam has a bulk porosity in the range of from 70 to 90% as specifically claimed in claim 37 and a slightly broader range in claim 25. These are specific claim limitations which again are in no way suggested by the prior art. The strut density is specified in claims 26 and 38. Clearly, these limitations are present in the

claims, discussed in the specification, and further distinguish the claimed subject matter over the prior art.

THE SECOND OBVIOUSNESS REJECTION

The rejection of claims 2 and 3 under 35 U.S.C. §103(a) as being unpatentable over the primary reference in view of the '897 patent as applied to claims 1, 4 -27, 32, 33 and 35-39 above, and further in view of Wu, the '562 patent, is also untenable and should be reversed for the reasons discussed above with respect to the combination of the primary reference and the '897 patent. The '562 patent does not overcome the deficiencies of the combination of references relied upon in the first obviousness rejection.

In the Final Rejection, the Examiner states that '562 patent is cited to teach a conventional size of grinding media. However, claim 2 on appeal is not concerned with milling powders using a grinding media. Instead, claim 2 is concerned with foaming a ceramic slip in a ball mill. This differs from the teaching of the '562 patent in that the starting material is a ceramic slip (not a starting powder) and in that the process produces a foam (not a milled powder). These are fundamental differences as would be appreciated by one of ordinary skill in the art to which the invention pertains. As the Examiner has acknowledged, the '562 patent is not concerned with foamed ceramics, nor synthetic bone materials for biomedical applications.

Applicants note that dependent claim 3 defines that the milling media have a diameter in the range of from 10 to 30 mm. This range is not disclosed in the '897 patent. While the '562 patent does mention 13 mm milling media, this is for grinding the starting powder, not for foaming a ceramic slip. There is no teaching or suggestion in any of the documents that such sized milling media could or should be relied on in the formation of a ceramic foam in accordance with the requirement of claim 3, let alone a ceramic foam for a synthetic bone material, where the pores have a modal diameter as specified by the claims on appeal.

The '562 patent relates to a method of improving the properties of ceramic green bodies. While the '562 patent does mention the use of a ball mill, this is not used to prepare a foamed ceramic. Instead, the ball mill is merely used to prepare (i.e. mill) the starting powders. This is clear from column 5, lines 31 to 42, were, the powders are milled and then separated from the grinding media. Only then is a slurry formed by adding deionized water. Thus, the '562 patent merely describes the conventional technique of using grinding media to mill starting powders. The '562 patent is not concerned with foamed ceramics, nor synthetic bone materials for biomedical applications.

In view of the above comments, it is considered that the disclosure of the '562 patent has been taken out of context and does not establish a prima facie case of obviousness for the claimed subject matter and this rejection should be reversed.

THE THIRD OBVIOUSNESS REJECTION

The rejection of claims 2 , 3 and 34 under 35 U.S.C. §103(a) as being unpatentable over the primary reference in view of the '897 patent as applied to claims 1, 4-27, 32, 33 and 35-39, above, and further in view of Nukada et al US 5,395,722, the '722 patent, is also untenable and should be reversed for the reasons discussed above with respect to the combination of the primary reference and the '897 patent. The '722 patent does not overcome the deficiencies of the first obviousness rejection.

With regard to the '722 patent, this reference is even further removed relating as it does to a electrophotographic photoreceptor. Even though the '722 patent does mention the use of a ball mill, this is used to prepare (i.e. mill) an organic perylene pigment. The '722 patent has nothing to do with ceramic powders let alone the preparation of a foamed ceramic bone material for biomedical applications. This reference was located by looking for claimed limitations and then searching the prior art for these limitations. This is improper hindsight reconstruction of the prior art to arrive

at the claimed invention. Accordingly, the Examiner's rejection should most respectfully be reversed.

IX. CONCLUSION

In view of the above arguments, the rejections of the claims on appeal should be reversed. The application should be passed to issue.

Respectfully submitted,

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APPENDIX

CLAIMS ON APPEAL

1. A method of producing a synthetic bone material for use in biomedical applications, said synthetic bone material comprising a macroporous ceramic foam which has an open foam structure containing pores with a modal diameter $d_{mode} \geq 100$ µm, which method comprises:

(a) forming a ceramic slip comprising a substantially homogeneous mixture of a ceramic particulate,

an organic binder in a liquid carrier, and

optionally one or more surfactant, wherein at least one surfactant is present if the organic binder does not function as a surfactant;

(b) foaming the ceramic slip using a ball mill; and

(c) heating the foamed ceramic slip at a temperature sufficient to substantially burn out the organic binder.

2. A method as claimed in claim 1, wherein foaming of the ceramic slip is achieved using a ball mill with milling media selected from alumina (Al_2O_3), enstatite ($MgSiO_3$) or zirconia (ZrO_2) balls.

3. A method as claimed in claim 2, wherein the balls of the milling media have a diameter in the range of from 10 to 30 mm.

4. A method as claimed in claim 1, wherein foaming of the ceramic slip is achieved using a ball mill in conjunction with gassing and/or a blowing agent.

5. A method as claimed in claim 1, wherein the ceramic slip has a viscosity in the range of from 30 to 100 mPas.

6. A method as claimed in claim 1, wherein the ceramic particulate is biocompatible.

7. A method as claimed in claim 1, wherein the ceramic particulate comprises one or more of hydroxyapatite, a substituted-hydroxyapatite, a glass, an AW-glass ceramic and/or alumina.

8. A method as claimed in claim 1, wherein the ceramic particulate has a d_{50} of from 1 to 300 μm.

9. A method as claimed in claim 1, wherein the ceramic particulate has a surface area in the range of from 5 to 200 m^2g^{-1}.

10. A method as claimed in claim 1, wherein the organic binder comprises one or more of poly (vinyl alcohol), poly (vinyl pyrrolidone), alginate, poly (lactic acid), poly (vinyl butyral), poly (ethylene glycol) and/or poly (vinyl acetate).

11. A method as claimed in claim 1, wherein the liquid carrier comprises water, propan-2-ol or trichloroethane.

12. A method as claimed in claim 1, wherein the organic binder is present in the liquid carrier in an amount of from 0.2 to 10 w/v%.

13. A method as claimed in claim 12, wherein the organic binder is present in the liquid carrier in an amount of from 0.5 to 6 w/v%.

14. A method as claimed in claim 1, wherein the ceramic slip comprises from 10 to 95 w/v% ceramic particulate.

15. A method as claimed in claim 14, wherein the ceramic slip comprises from 20 to 90 w/v% ceramic particulate.

16. A method as claimed in claim 1, wherein the ceramic slip further comprises one or both of a dispersant and/or a defloculant.

17. A method as claimed in claim 1, wherein prior to burn-out of the organic binder the liquid carrier is allowed to evaporate from the foamed carrier slip.

18. A method as claimed in claim 17, wherein the foamed ceramic slip is heated at a temperature in the range of from 20 to 100°C to facilitate evaporation of the liquid carrier prior to burn-out of the organic binder.

19. A method as claimed in claim 17, wherein the concentration of the organic binder in the liquid carrier is selected such that the percentage of binder remaining after substantially all of the liquid carrier has been evaporated is from 0.5 to 10 w/w%.

20. A method as claimed in claim 19, wherein the concentration of the organic binder in the liquid carrier is selected such that the percentage of binder remaining after substantially all of the liquid carrier has been evaporated is in the range of from 1 to 6 w/w%, preferably from 1 to 4 w/w%.

21. A method as claimed in claim 1, wherein the foamed ceramic slip is cast in a mould having a surface coated with a release agent.

22. A method as claimed in claim 1, wherein burn-out of the organic binder is carried out at a temperature in the range of from 150 to 700°C.

23. A method as claimed in claim 1, further comprising sintering the ceramic foam following burn-out of the organic binder.

24. A method as claimed in claim 23, wherein sintering is carried out at a temperature in the range of from 500 to 1600°C.

25. A method as claimed in claim 23, wherein the sintered ceramic foam has a bulk porosity in the range of from 40 to 95%.

26. A method as claimed in claim 1, wherein the sintered ceramic foam has a strut density in the range of from 60 to 95% of the theoretical density of the ceramic.

27. A method as claimed in claim 23, wherein the sintered ceramic foam has a modal pore size in the range of from 100 to 2000 μm.

32. A method of producing a synthetic bone material as claimed in claim 1, wherein the ceramic slip preferably has a viscosity in the range of from 15 to 200 mPas.

33. A method as claimed in claim 8, wherein the ceramic particulate has a d_{50} of from 1 to 15 μm.

34. A method as claimed in claim 3, wherein the balls of the milling media have a diameter in the range of from 15 to 25 mm.

35. A method as claimed in claim 13, wherein the organic binder is present in the liquid carrier in an amount of from 0.5 to 4 w/v%.

36. A method as claimed in claim 15, wherein the ceramic slip comprises from 40 to 80 w/v% ceramic particulate.

37. A method as claimed in claim 25, wherein the sintered ceramic foam has a bulk porosity in the range of from 70 to 90%.

38. A method as claimed in claim 26, wherein the sintered ceramic foam has a strut density in the range of from 70 to 90% of the theoretical density of the ceramic.

39. A method as claimed in claim 27, wherein the sintered ceramic foam has a modal pore size in the range of from 100 to 1000 μm.